Law on
Genetically Modified Organisms

C h a p t e r o n e
GENERAL PROVISIONS

Art. 1. This law shall settle the conditions and the order for creating, testing, releasing to the market and importing genetically modified organisms (GMO) and their products within the territory of The Republic of Bulgaria

Art. 2. /1/ This law shall not be applied for creating, releasing to the market and importing organisms, created by traditionally used methods and techniques of genetic modification.

/2/ This law shall not be applied with regard to human organism.

C h a p t e r t w o
STATE COMMITTEE ON GENETICALLY MODIFIED ORGANISMS

Art. 3. /1/ The authority for fulfillment of permitting and controlling functions for the enforcement of this law shall be the State committee on genetically modified organisms (SCGMO) with the Minister of Agriculture and Forests, hereinafter called “the State Committee”.

/2/ The State Committee shall be a juridical person on budget support.

/3/ By a decree for creating the State Committee the Council of Ministers shall determine the way of its functioning and the necessary administrative organization for realizing its activity.

/4/ The activity, the structure, the organization of work and the membership of the State Committee and its administration shall be defined by a Structure Rules, approved by the Council of Ministers.

/5/ The State Committee shall be a collective authority, which is composed by a chairman and 15 members.

/6/ The Council of Ministers shall appoint the members of SCGMO at a proposal by the Minister of Agriculture and Forests.

/7/ Releasing of SCGMO members shall be done by a decision of the Council of Ministers at a proposal by the chairman or at a person’s request.

/8/ The Secretary of the State Committee shall be a scientist having academic rank in the sphere of biotechnology.

/9/ The State Committee on Genetically Modified Organisms shall accept rules for its work.

Art. 4. /1/ Funds for the activity of the State Committee shall be gathered from:

1. Fees;
2. 30 per cent of the fines and property sanction envisaged by this law;
3. Interests;
4. Donations;
5. Target receipts;
6. Financial assistance by international organizations;

/2/ Incomes under paragraph 1 shall be spent for:

1. Financing the activity;
2. Financing projects connected with the control over GMO;
3. Other expenses.

/3/ Unspent funds shall be considered transferable reminder at the end of the reported year, which shall be used by SCGMO during the next year.

Art. 5. /1/ The State Committee on the genetically modified organisms shall:

1. Grant, refuse to issue and withdraw:
   a. license for working with SCGMO in a controlled system;
   b. permissions for allowing the spread of GMO in the environment.
   c. permission for releasing on the market of products, which are or contain GMO.
   d. permissions for import of products, which are or contain GMO.
2. Keep registers under item 1, letters "a", "b", "c", and "d".
3. Define the level of risk when working with GMO and adjust it as necessary.
4. Identify accredited laboratories, in which analyses and studies about the needs on the control under this law are made.
5. Withdraw in favor of the state all GMO and materials connected with their creation and testing, which endanger people's health or the environment.
6. Have the right to stop respective activity with GMO for a period of one to six months for violations that damage people's health or the condition of the environment.
7. Gather fees for issuing licenses and permissions under this law.
8. Issue a quarterly bulletin about the activity of SCGMO.
9. Organize public discussions on GMO-related issues in cases they are of wide public interest.
10. Exercise other functions, assigned by a law.

/2/ SCGMO can create expert councils and/or groups to assist with its activity.

Art. 6. The members of SCGMO shall not have the right to spread information, facts and circumstances, which they have learned in their capacity of SCGMO members.

Art. 7. The register under Art. 5, Para 1, item 1, letter "a" shall contain:

1. Name, address, ID card number, social number for physical persons; title, headquarters, certificate for current condition, Statistical number, tax registration - for juridical persons;
2. Address and description of the site where the creation of GMO will take place;
3. Description of the kind and the volume of work on creating GMO;
4. Identifying the level of risk;
5. Risk assessment;

6. Purpose for creating GMO and expected results;
7. Type of GMO, which will be worked with;
8. Number and date of the official decisions for license granting and withdrawal;
9. Number and issuance date of the license;
10. Information about restoring the license rights.

Art. 8. The register under Art. 5, Para 1, item 1, letters "b" and "c" shall contain:

1. Name, address, ID card number, social number for physical persons; title, headquarters, certificate for current condition, Statistical number, tax registration - for juridical persons, who were granted permission;
2. Number and date, under which the applicant's file has been registered;
3. Name of genetically modified organisms and products;
4. Type of genetic modification;
5. Place of use and sphere of spreading;
6. Spreading term;
7. Number and date of the official decisions for testing and releasing to the market;
8. Number and date for the approval for testing and releasing to the market;
9. Number and date of the official decisions for giving and depriving the permissions;
10. Information for restoring the permit rights.

Art. 9. The register under Art. 5, Para 1, item 1, letter "d" shall contain:

1. Name, address, ID card number, social number for physical persons; title, headquarters, certificate for current condition, Statistical number, tax registration - for juridical persons, and contact information for the exporter and the importer;
2. Number and date of the official decisions for granting and withdrawal of the license;
3. Date of issuing the license;
4. Name, GMO identification data, as well as the national classification, if it exists, about bio-safety level for GMO in the exporting country;
5. Expected date or dates for trans-boundary moving, if they are known;
6. Centers of origin and centers of genetic spreading, if they are known, of the organism that received the genetic material; description of habitats, where the organisms can subsist or breed.
7. Supposed use of GMO or the products which it contains;
8. GMO quantity or volume, which will be transmitted;
9. Information about the regime of GMO in the exporting country (permission for release, restrictions, interdictions in the exporting country, the reason or the reasons for the interdiction);
10. Results and purposes for every application from the exporter to other countries, concerning GMO that is subject to transmission.

Art. 10. The registers under art. 7, 8, and 9 shall be public.

Art. 11. /1/ The Council of Ministers shall accept a decree for approving the rate for the fees, which are collected for issuing licenses and permissions.

/2/ The fees for issuing licenses and application forms are paid upon their receipt by the applicants and shall be transferred to the SCGMO account.

C h a p t e r t h r e e
CONTROL

Art. 12. /1/ The following shall be subject to state control under this law:

1. All stages of the creation, testing, releasing to the market, import, export and transit transportation of GMO and their products;
2. The sites, the transport, technical and material means and equipment, connected to the work with GMO and their products;
3. The biological material, used when creating GMO and their products;
4. The processes in creating and testing GMO and their products;
5. Storing and destruction of GMO, their products and waste;
6. Presenting, advertising and labeling GMO and their products;
7. The methods and means for storing and packing GMO and their products.
8. The hygiene of persons, who get in touch with GMO and their products, as well as the waste of GMO, released when working with GMO in a closed system and during their spreading in the environment.

/2/ The state control shall be done systematicaly, periodically or in cases of doubt, without advance notification.

Art. 13. The state control shall consist of one or more of the following activities:

1. Checking the subjects to control under Art. 12, Para 1.
2. Taking samples and models and performing analyses and tests.
3. Control on personnel's hygiene.
4. Control on the safety measures.
5. Review of documentation.
6. Checking on the introduced control systems and their effectiveness.

Art. 14. /1/ The control under Art 12, Para 1 shall be performed by the state control authorities determined by the National Health Law, the Law on Veterinarian and Medical Activity, the Plant Protection Law, the Environmental Protection Law, the Law on Sowing and Seeding Material, the Law on Wine and Alcoholic Drinks, the Customs Law, the Ministry of Internal Affairs Law, the Law on Customer Protection and Trading Rules and by SCGMO, under the conditions and in the way set by this law, as follows:

1. The state control authorities with the Ministry of Agriculture and Forests shall exercise control on the safety and the quality of GMO and their products.
2. The state control authorities with the Ministry of Environment and Waters shall exercise control on the influence of GMO and their products on the environment.
3. The state control authorities with the Ministry of Health shall exercise control on the influence of GMO, their products, foodstuffs and medicines on the human organism.
4. The state control authorities with the Ministry of Finance shall exercise control on the import, the export and the transit transport of GMO and their products.
5. The state control authorities with the Ministry of Economy shall exercise control on the industrial produce and trade with GMO and their products.
6. The state control authorities with the Ministry of Internal Affairs shall exercise control on the transport of GMO, their products and waste and provide the needed support to the control authorities.

/2/ The control authorities under Para 1 shall be obliged to submit the materials on violations to SCGMO within 14 days of the establishment of the violation.

Art. 15. /1/ The state control authorities shall have the right:

1. Of free access to all the sites under Art. 12, Para 1.
2. To demand and check information and documents on the activity, connected with GMO and their products.
3. To take samples and models for laboratory analyses and tests.
4. To give compulsory prescriptions when establishing violations of the safety measures in the process of creating and testing GMO and their products and destroying the GMO waste.
5. To stop the exploitation of production facilities and parts of them in the cases under Art. 35 and 40.
6. To stop the spreading of GMO and their products, which directly or indirectly endanger human health and the environment and to issue an order for their destruction.
7. To control the withdrawal of GMO and their products from the market in the case under art. 40.
8. To restrict the access to the sites under interdict by placing notifying symbols.
9. To draw up statements for establishing the administrative violations.

/2/ The control authority officials shall not have the right to spread the information, facts and circumstances, which were made known to them while performing their work.

Art. 16. /1/ The persons, creating, testing and producing GMO and their products, shall be obliged to control each one of these activities. The destruction of the waste from GMO shall also be subject to control.

/2/ The persons under Para 1 shall preliminarily develop safety regulations and extreme situation action plan, which shall be presented to SCGMO for approval. The extreme situation action plan shall be presented to the safety services of the municipality, on whose territory the work is performed.

Art. 17. /1/ The persons, creating, testing, and producing GMO and their products shall be obliged to appoint a safety expert, who shall have a university degree in the field of biotechnology and a minimum of 2 years experience in the work with GMO.

/2/ When ensuring the safety measures, the persons, working with GMO shall co-ordinate their activities with the safety expert and with the project leader under Art. 25, Para 1, item 3.

C h a p t e r f o u r
WORK WITH GENETICALLY MODIFIED ORGANISMS IN A CONTROLLED SYSTEM

Art. 18. Work with GMO in a controlled system shall be done only by persons, who have received a license for this activity from SCGMO.

Art.19. /1/ The license application shall contain:

1. Name, address, ID card number, social number for physical persons; title, headquarters, certificate for current condition, Statistical number, tax registration - for juridical persons;
2. Address and description of the site, where GMO will be created;
3. Identifying the level of risk;
4. Purpose of the GMO creation and expected results;

5. Type of GMO, which will be worked with;

/2/ The following shall be enclosed to the application:

1. Description of the type, method and volume of the work on the creation of GMO;
2. Risk assessment;
3. Safety measures;
4. Extreme situation action plan;
5. Information about the way of storing and destruction of waste from GMO;
6. Names and qualification of the personnel directly engaged in creating GMO.
7. Document for paid fee.

/3/ The applicant shall provide in the application justified specification of the information that shall be considered confidential. The information under Para 1, items 1, 2, 3, 4 and 5 and Para 2, items 2, 3, 4 and 5 shall not be considered confidential.

/4/ Where incomplete or inaccurate data are provided under Para 1, SCGMO shall notify the applicant within one month and shall not consider the application until their correction.

Art. 20. /1/ Within two months from handing the application or the correcting the gaps under Art. 19 Para 2, SCGMO shall issue or motivate the refusal to issue a license. The license shall contain the information under Art. 7, items 1-7.

/2/ For identifying the level of risk, SCGMO can request from the applicant additional information under Art. 19, Para 1, items 3,4 and 8.

/3/ The applicant shall provide the requested information to the SCGMO within 30 days from the request.

/4/ The lack of reply within the term under Para 1 shall be considered implicit denial.

/5/ The denial under Paras 1 or 4 can be appealed in accordance with the order under the Administrative Procedures Law.

Art. 21. Work with GMO in a controlled system shall only be performed in observance of the necessary safety measures, that ensure the safety based on the respective level of risk.

Art. 22. After being issued a license for work with GMO in a controlled system, persons under Art. 18 shall be obliged to inform immediately SCGMO for changes in the level of risk of the work on creating GMO.

Art. 23. /1/ Persons under Art 18, working with GMO shall be obliged to appoint a project leader.

/2/ The project leader shall be a scientific worker who has an academic rank in the area, which is subject to this law.

Art. 24. The project leader shall be obliged to:

1. Propose to the person under Art. 18 to determine the risk level for the concrete project.
2. Inform the workers, engaged with the project about the safety measures and the actions in extreme situations.
3. Supervise the application and execution of safety measures.
4. Propose to the authorities under Art. 14 to impose sanctions for safety measure violations.

5. Keep records and ensure the proper registration of the work on creating GMO.

Art. 25. /1/ The records under Art. 24, item 5 shall contain:

1. Number and date;
2. Name of the owner and location of the genetic installation;
3. Name of the project leader and the person in charge for the safety;
4. Description of the work on creating GMO;
5. The level of risk in the work on creating GMO;
6. Method ensuring GMO safety;
7. Beginning and end of the work on creating GMO;
8. Information for extreme situations;
9. The names of the persons who are directly engaged in the work on creating GMO;
10. Signature of the project leader.

/2/ If a correction to the record needs to be made, the date of the correction shall be specified and the project leader shall sign again.

/3/ The records shall be kept for at least 5 years after the creation of GMO.

/4/ The records under Art. 24 item 5shall be made available to SCGMO and to the state control authorities.

Art. 26. When changing the owner of the controlled system, the issued licenses for work with GMO in a controlled system shall remain valid. The new owner shall be obliged to immediately inform SCGMO for the occurred changes in writing.

Art. 27. After being issued a license for work with GMO in a controlled system, whenever a change of the risk level need to be done, the person under Art. 18 shall informs SCGMO, which shall prescribe additional safety measures or stop the work with the respective GMO and issue an order for their destruction. [*almost the same as Art 22??? - Irena*]

Art. 28. The persons under Art. 18 shall be obliged to destroy or store the remains and waste from the work with GMO.

Art. 29. In cases of incident during the work with GMO in a controlled system the persons under Art. 18 shall be obliged to inform immediately SCGMO and provide information about:

1. The circumstances, under which the failure has happened;
2. Characteristics and amount of the affected GMO;
3. Measures applied;
4. Information, necessary for the assessment of the failure impact on the human health and the environment.

Art. 30. /1/ The conditions and order of working with GMO in a controlled system and of destruction or storing the waste thereof, shall be determined with a Council of Ministers Decree at a proposal by the Minister of Environment and Waters.

/2/ The order and requirements for securing the waste from GMO shall be determined with an order by the Minister of Agriculture and Forests, the Minister of Environment and Waters and the Minister of Health.

Chapter five
ALLOWING GMO IN THE ENVIRONMENT

Art. 31. /1/ GMO shall be allowed in the environment only after issuing a permission by SCGMO based upon a submitted application.

/2/ The application shall contain:

1. Name, address, ID card number, social number for physical persons; title, headquarters, certificate for current condition, Statistical number, tax registration - for juridical persons;
2. Title of genetically modified organisms and products;
3. Type of the genetic modification;
4. Place of use and area of spreading;
5. Spreading term.

/3/ The following shall be attached to the application under Para 1:

1. Description of the method of obtaining GMO;
2. Information of the type of genetic modification of GMO;
    a. Primary organism, which the genetic material is obtained from.
    b. The organism that received the genetic material;
    c. Content of the genetic material;
    d. Method for identifying GMO;
3. Bibliographic reference about GMO
4. Information about the qualification of the personnel, that shall perform the testing.
5. Information about the testing places and sites.
6. Term, duration and frequency of testing.
7. Areas of application of the tested GMO.
8. Information about the condition of the places and sites, before, during and after the testing.
9. Information about the targeted and the non-targeted impacts on the ecosystems from the testing of GMO;
10. Information about the level of risk of GMO on the humans;
11. Information about the effect of the environment on the subsistence and breeding of GMO.
12. Information about the possibilities for transfer of genes from GMO to organisms in the environment.
13. Information about the observation and control system when allowing the spreading of GMO, about the extreme situation action plans and about waste treatment.
14. Description of the procedure on completing the testing.
15. Information about the methods and actions for neutralizing and restricting the spreading of GMO within and/or outside the areas of testing.
16. Description of future preservation of the testing places and sites, for obligatory destruction of GMO and testing products, the term for observing the places and/or sites after completing the testing.
17. Information and bibliographic reference about the testing of similar or the same GMO, performed by the applicant or by other persons in the country or abroad.

/4/ The applicant shall provide in the application justified specification of the information that shall be considered confidential. The information under Para 2, items 1, 2, 4 and 5 and under

Para 3, items 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16 and 17 shall not be considered confidential.

/5/ Where incomplete or inaccurate data are provided under Para 1and Para 2, SCGMO shall notify the applicant within one month and shall not consider the application until their correction.

Art. 32. /1/ Within one month from submitting the application SCGMO can request from the applicant additional information under Art. 31 Para 3. The applicant shall be obliged to provide to SCGMO the requested information within 30 days after the request. If the applicant fails to keep this term SCGMO shall not consider the application.

/2/ Before issuing the permission SCGMO can request statements from other interested agencies and organizations, as well as to hold public hearings.

Art. 33. /1/ Within three months from submitting the application SCGMO shall issue or motivate the refusal to issue a permission for testing. This term of three months shall not include the terms under Art. 32, Para 1.

/2/ The lack of reply within the term under Para 2 [*it is Para 2 in the Bulgarian - Irena*] shall be considered implicit denial.

/3/ The denial under Para 1 and Para 2 can be appealed in accordance with the order of Administrative Procedures Law (APL).
Of permission can be appealed in accordance with the order of APL. [*in the original - Irena*]
Art. 34. The permission for allowing the spreading of GMO shall be issued for a period of ten years. During this term the person shall inform SCGMO annually about the results from the interaction between GMO and the environment and human and shall make risk assessment.

Art. 35. /1/ If during the testing of GMO and before issuing the permission under Art. 33, Para 2 or Art. 32, Para 2, changes occur, which can have negative adverse effect on human health and the environment, the applicant shall immediately inform SCGMO and undertake all the necessary measures for protecting human health and the environment.

/2/ If during the testing, releasing GMO in the environment or after issuing the permission under Art. 33, Para 2 or Art. 32, Para 2, a reliable information is received for the harmful effect on the environment or on the human health, SCGMO shall make check-ups within two months and if necessary shall change the conditions of the permission, and it may delay or cease the spreading.

Art. 36. The conditions and the order for letting, testing and spreading GMO in the environment are settled by the order from the Council of Ministers.

Chapter six
RELEASING GMO AND THEIR PRODUCTS TO THE MARKET

Art. 37. /1/ Releasing of GMO and their products to the market shall be done after issuing a permission by SCGMO based on a submitted application.

/2/ The application shall contain:

1. Name, address, ID card number, social number for physical persons; title, headquarters, certificate for current condition, Statistical number, tax registration - for juridical persons for the producer or the distributor;
2. The product name and the names of GMO, which it contains.
3. Product features;
4. Instructions for product use;
5. Type of environment and/or geographic area, which the product is designed for;
6. Area of application;
7. Information about the genetic modification;
8. Information about the expected produce and/or import (quantity, number, areas);
9. Suggestion for packing;
10. Design for a label;
11. General risk assessment in a format approved by a regulation under Art. 45.
12. Information and bibliographic reference about the testing of similar or the same GMO, performed by the applicant or by other persons in the country or abroad;

/3/ The applicant shall provide in the application justified specification of the information that shall be considered confidential. The information under Para 1, items 1, 2, 3, 4, 5, 6, 8, 9, 10 and 11 shall not be considered confidential pg..

/4/ The applicant shall provide to SCGMO information about previous releasing to the market.

/5/ Where incomplete or inaccurate data are provided under Para 2, SCGMO shall notify the applicant within one month and shall not consider the application until their correction.

Art. 38. /1/ Within three months from submitting the application SCGMO shall issue or motivate the refusal to issue a permission.

/2/ The lack of reply within the term under Para 1 shall be considered implicit denial.

/3/ The denial under Para 1 and Para 2 can be appealed in accordance with the order of APL.

Art. 39. The permission for releasing to the market shall contain:
1. Date of issuing the permission;
2. Permission number;
3. Permission holder;
4. Product name;
5. Area of application;
6. Packing;
7. Label;
8. Conditions and method of storing.

Art. 40. /1/ In case of establishing or receiving reliable information about harmful effect on the human health and/or the environment, the applicant shall be obliged to immediately inform SCGMO and undertake all the necessary measures for protecting human health and the environment.

/2/ If after issuing the permission for spreading the product a reliable information is received about the harmful effect on human health or the environment SCGMO shall make check-ups

within two months and according to the results shall withdraw the permission and issue an order for withdrawing the product from the market.

Art. 41. /1/ A product which is GMO or contains GMO shall have a label, explicitly specifying the presence and the name of GMO, number and date of the permit.

/2/ When the content of GMO in the product is less than 1%, putting a label under Para 1 shall not be obligatory.

Art. 42. The application for import of GMO and their products intended for direct use like food or fodder, or for processing, besides the data under Art. 37, Paras 2 and 3 and the application for import of GMO and their products, not intended for direct use like food and fodder, or for processing, besides the data under Art. 31, Paras 2 and 3 shall contain:

1. Name, address and contact information for the exporter;
2. Name, address and contact information for the importer;
3. Quantity or volume of GMO, which will be transported;
4. Expected date or dates for trans-boundary moving, if they are known;
5. Centers of origin and centers of genetic spreading, if they are known, of the organism that received the genetic material; description of habitats, where the organisms can subsist or breed;
6. Taxonomic status, common name, collection or receipt point and characteristic of the primary organism, which the genetic material is obtained from.
7. Contents of the genetic material;
8. Method for identifying GMO;
9. Approved use of GMO;
10. Information about the regime of GMO in the exporting country (permission for release, restrictions, interdictions in the exporting country, the reason or the reasons for the interdiction);
11. Results and purposes for every application from the exporter to other countries, concerning GMO that are subject to import;
12. Declaration for accuracy of the submitted information;

Art. 43. /1/ SCGMO shall issue or motivate its refusal to issue permissions for import of GMO and their products within three months from the date of filing the application.

/2/ The lack of reply within the term under Para 1 shall be considered implicit denial.

/3/ The denial under Paras 1 and 2 can be appealed in accordance with the order under the Administrative Procedures Law.

Art. 44. The requirements to the products that are or contain GMO shall be determined with an order by the Council of Ministers.

Chapter seven
LEVEL OF RISK ASSESSMENT

Art. 45. /1/ The creation, testing, releasing to the market and import shall be done at four levels of risk:

1. First level of risk;

2. Second level of risk;
3. Third level of risk;
4. Forth level of risk.

/2/ The level of risk shall be determined on the basis of risk assessment.

/3/ The risk assessment shall be made for every genetically modified organism individually.

/4/ The conditions and the order for preparing the risk assessment shall be determined with a Council of Ministers' order.

Chapter eight
WITHDRAWAL OF LICENSES AND PERMISSIONS

Art. 46. /1/ SCGMO shall withdraw the issued licenses under Art. 20:

1. when the requirements under Art. 22-29 have not been observed;
2. when the conditions for safe work with GMO have been violated.

/2/ The decision for withdrawing the license or the permissions shall be motivated and sent to the interested person in writing. A stipulation of advance execution shall be included in the decision and it shall be subject to immediate implementation.

/3/ The decision under Para 2 can be appealed in accordance with the order under the Administrative Procedures Law.

/4/ The appeal of the decision shall not stop its action.

Art. 47. The State Committee shall withdraw the issued permissions under Art. 33 Para 1:

1. when the conditions for safe work with GMO have been violated;
2. when the requirements under Art. 35 Para 1 have not been observed.

Art. 48. /1/ The State Committee shall withdraw the issued permissions under Art. 38 Para 1:

1. when the conditions of the permission under Art. 39 item 5, item 6, item 7, and item 8 and Art. 42 have not been observed;
2. when requirements under Art. 40, Para 1 have not been observed;
3. when a declaration with incorrect content has been filed;
4. when safety conditions have been violated.

/2/ When the imported GMO and their products fail to meet the requirements, settled in the permission under Art. 43, Para 1, SCGMO shall confiscate them in favor of the state and shall deal with them in accordance with the conditions and order, set with a Council of Ministers Decree.

Chapter nine
ADMINISTRATIVE AND PENAL PROVISIONS

Art. 49. Anyone who obstructs the activity of the control authorities under Art. 13, Para 1 shall be charged from 1,000 to 5,000 levs, and if the violation is repeated, the fine shall range from 10,000 to 20,000 levs.

/2/ When the violation under pg. 1 is made by a juridical person, the property sanction shall range from 20,000 to 50,000 levs, if the violation is repeated - from –100,000 to 150,000 levs.

Art. 50. For violations of Art. 16, Para 2, Art. 17, Para 1, Art. 22, Art. 23, Paras 1 and 2, Art. 35 Para 1 and Art. 41 Para 1 or of the stipulation of a Regulation on applying the law a person shall be charged from 5,000 to 10,000 or property sanction shall be imposed ranging from 20,000 to 30,000. If the violation is repeated, the fine shall range from 10,000 to 20,000, and the property sanction - from 30,000 to 50,000.

Art. 51. /1/ The violations shall be established with statements, drawn by the authorities under Art. 14 of this law.

/2/ The penalty ordinances shall be issued by the Chairman of SCGMO or by the authorities envisaged in the laws under Art. 14, Para 1.

/3/ The establishment of violations, the issuance, the appealing and the execution of penalty ordinances shall be pursuant to the Administrative Violations and Penalties Act.

ADDITIONAL PROVISION

§1. By the sense of this law:

1. "organism" shall be every biological object, for the exception of humans, that is capable of transferring and recreating genetic material, including sterile organisms, viruses and viroids;
2. "genetically modified organism" shall be an organism, that has new combination of genetic material, obtained by using the method of recombined DNA, as well as the techniques for direct introduction to the organism of genetic material, obtained outside the recipient organism and introduced in it by the techniques like micro- and macro-injection, electroporation, bombing, and co-cultivation with Agrobacterium.
3. "work with genetically modified organisms in a controlled system" shall be a production, breeding, use, storage, destruction and securing the GMO, before their release;
4. "controlled system" shall be a device, facility or other physical structure, that includes genetically modified organisms and that is controlled with special measures, that restrict effectively their contact with the outer surrounding and their influence on it;
5. "allowing the spreading of GMO" shall be a purposeful removal of GMO from the controlled system, without using physical, chemical and/or biological barriers, applied for restricting their contact with other organisms and the environment;
6. "releasing GMO to the market" shall be providing to third individuals products that are or contain GMO;
7. "Export" shall be the intentional trans-boundary transfer of products that are or contain GMO from Bulgaria to other countries.
8. "Import" shall be the intentional trans-boundary transfer of products that are or contain GMO from other countries to Bulgaria.
9. "Product from GMO" shall be a product that contains GMO or is obtained through the recombined DNA technology and which contains or does not contain the respective biochemical component depending on its purification level.
10. "Repeated violation" shall be a violation, that is made within one year from entering into force [*of the ordinance? - Irena*], with which the offender has been punished for the same violation.
11. "Traditionally used methods and techniques of genetic modification" shall be: sexual hybridization (close and distant);experimental mutagenesis; polyploidion; tissue cultures (colonial micro-breeding, immuno-diagnostics, embriocultures and "in-vitro" fertilization,

somatic hybridization) and natural processes like conjugation, transduction and transformation.

12. "Level of risk" shall be an influence and/or reflection on human health and the environment to a degree, when the impacts can or have to be taken into consideration;
13. "Risk assessment" shall be the assessment of the potential direct, indirect, immediate and delayed harmful impacts on the health of the human and the animals, the environment and the biological diversity
    - "direct impact" shall be the influence of GMO on human health or the environment, which is a result of GMO itself and which does not occur as a result from events with casual connection between them;
    - "indirect impact" shall be the influence or GMO on human health or the environment, which is a result of events with casual connection between them: in interaction with other organisms, transfer of genetic material or change in the management. It is possible that indirect influence is delayed;
    - "immediate impact" shall be the influence of GMO on human health or the environment, which is manifested at the release of GMO. The immediate influence can be direct or indirect;
    - "delayed impact" shall be the influence of GMO on human health or the environment, which can not be noticed when releasing GMO and does not show as a direct or indirect influence at a later stage or after stopping the release.
14. "Incident" shall be every event that occurs when using GMO and products, where there is a significant involuntary release of GMO and that can bring to an immediate or delayed danger for the health of the human and the animals, the environment and the biological diversity.

CONCLUDING PROVISIONS

§2. The Regulations for the application of this law shall be issued within six months from its entering into force.

§3. This law shall enter into force within three months from it publication in State Gazette.

MOTIVES
TO THE DRAFT LAW ON GENETICALLY MODIFIED ORGANISMS

The draft Law on genetically modified organisms is aimed at settling the conditions and the order of work with genetically modified organisms, their release in the environment and offering the market products, that are or contain genetically modified organisms. The following EU legislation are operational in the field of genetically modified organisms: Directive 90/220 and Directive 94/15 concerning the intentional releasing of genetically modified organisms in the environment, Regulation 258/97 concerning new foodstuffs and new food components, as well as Directive 98/95 concerning the common market of seeds of genetically modified crops.

By introducing the stipulations of those acts, the Draft Law provides the legislative framework and arranges the mandates, related to the conditions and the order of creating, testing, releasing to the market and importing genetically modified organisms and their products within the territory of the Republic of Bulgaria.

The Draft Law creates a State Committee on Genetically Modified Organisms, which is a juridical person on a budget support. The powers of the State Committee and its functions are regulated in detail.

A special chapter is elaborated /Chapter 3 from the Draft Law/, which regulates the state control over:

1. The stages of creating, testing, releasing to the market, importing, exporting and the transit transportation of GMO and their products;
2. The sites, the transport, technical and material means and equipment, related to the work on GMO and their products;
3. The biological material, used when creating GMO and their products;
4. The processes of creating and testing GMO and their products;
5. The storing and the destruction of GMO, their products and waste;
6. The methods and the means for storing and packing GMO and their products;

The Draft Law envisages the creation, testing, releasing to the market and the import to be done at four levels of risk, and the risk assessment to be made for every genetically modified organism individually.

The Draft Law defines the “risk assessment” as an assessment of the potential direct, indirect, immediate and delayed harmful impacts on the health of the human and the animals, the environment and the biological diversity.

SUBMITTED BY:

VENTSISLAV VARBANOV – Member of Parliament from the UDF Parliament Group